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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/446,711	04/03/2000	FRANCE ALLARD	P04334US00	2785

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EXAMINER	
COLLINS, CYNTHIA E	

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 05/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/446,711	ALLARD ET AL.	
	Examiner	Art Unit	
	Cynthia Collins	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 February 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,9-14,16-22,24 and 38-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,9-14,16-22,24 and 38-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's submission filed on February 23, 2004 has been entered.

Claims 4-8, 15, 23 and 25-37 are cancelled.

Claims 1, 9-11, 14, 16, 24 and 38-39 are currently amended.

Claims 40-41 are newly added.

Claims 1-3, 9-14, 16-22, 24 and 38-41 are pending and are examined.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

Claims 1-3, 9-14, 16-22, 24 and 38-39 remain rejected, and claims 40-41 are rejected, under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of increasing or inducing cold or freezing tolerance in the wheat cultivar Glenlea, said method comprising simultaneously acclimating the plant and increasing the concentration of betaine in the plant by administering a betaine or a derivative thereof, wherein the lethal temperature of the plant is decreased, wherein the acclimation temperature is 6° C during the day and 2° C during the night, and wherein the betaine or derivative thereof is at a concentration of 100 to 250 mM, does not reasonably provide enablement for other methods of increasing or inducing cold or freezing tolerance in other plants, for the reasons of record set forth in the office action mailed September 23, 2003.

Applicant's arguments filed February 23, 2004, have been fully considered but they are not persuasive.

Applicants point to Figures 1 and 2 as examples of enabling support in the specification. Applicant also points out that the application discusses a method using wheat generally because one skilled in the art would appreciate that the claimed method would work with different wheat cultivars. Applicants point in particular to page 6 as disclosing that the Frederick wheat cultivar, like the Glenlea wheat cultivar, also has increased betaine during cold acclimation. (reply pages 8-9) Applicants also point to the experimental results disclosed for golf turf (page 10 and Figures 4 and 5) and barley (page 8) directly showing that the claimed methods work with at least three graminae species. (reply page 9) Applicants additionally point out that the application describes the use of various types of betaines, and that the application at pages 3, 4, 8 and in Figure 1 for example, provides multiple examples of useful betaine doses and dosage regimes. Applicants further assert that one skilled in the art would be able to practice the claimed invention at other acclimation temperatures, because the specification indicates that the plant is acclimated to a temperature not lower than the coldest temperature that the plant can withstand, and because information about the cold-hardiness of commercially import plants should be readily available or may be determined according to methods disclosed in the specification (reply pages 10-11). Applicants further point out that the specification provides, at pages 9-10 and Figure 4 for example, detailed support for improving photosynthetic capacity and overall physiology at cold temperature, as well as for increasing or inducing salinity and water stress tolerance (reply page 11).

The rejection is maintained because the specification does not provide sufficient guidance for one skilled in the art to practice the full scope of the claimed invention without undue experimentation. While the specification provides guidance with respect to a method of

increasing or inducing cold or freezing tolerance in the wheat cultivar Glenlea, the specification does not provide sufficient guidance for one skilled in the art to modify the disclosed method for use with other wheat cultivars or other graminae species. Such guidance is necessary because, as discussed previously at pages 7-8 of the office action mailed September 25, 2001, the effect of betaine accumulation in plants is unpredictable, since different plant species may respond differently to the application and accumulation of glycine betaine.

With respect to the disclosure at page 6 that the Frederick wheat cultivar, like the Glenlea wheat cultivar, also has increased betaine during cold acclimation, the specification at page 6 also discloses that the Frederick and Glenlea wheat cultivars differ in their levels of freezing tolerance, their basal betaine level before cold acclimation, and their betaine level after cold acclimation, with the Frederick wheat cultivar exhibiting higher levels of freezing tolerance, basal betaine level before cold acclimation, and betaine level after cold acclimation as compared to the Glenlea wheat cultivar. The specification does not provide guidance with respect to how to modify the disclosed method for use with other wheat cultivars such as the Frederick wheat cultivar which exhibits higher levels of freezing tolerance, basal betaine level before cold acclimation, and betaine level after cold acclimation as compared to the exemplified wheat cultivar.

With respect to the disclosure of experimental results disclosed for golf turf at page 10 and in Figures 4 and 5, the disclosed results do not appear to have been achieved using the claimed method. The specification at page 10 lines 17-20 discloses that "betaine application early in the fall improves the performance of golf turf and consequently increased winter survival. The betaine-treated turf showed a rapid regrowth in the spring indicating a higher

winter survival rate and healthier plants at spring which have a better regrowth rate." Figures 4 and 5 illustrate the effects of treating golf turf with betaine "three times at a weekly interval in fall". The specification does not disclose a method in which golf turf plants are exposed to a temperature not lower than the coldest temperature the plants are capable of withstanding for a time sufficient to induce cold or freezing tolerance and administering betaine to the plants to increase betaine concentration in the plant during cold acclimation to induce cold or freezing tolerance.

With respect to the disclosure of experimental results disclosed for barley at page 8, which indicates that "the combined treatment of low temperature and betaine was as efficient in this species as in wheat to improve FT", the Office maintains the disclosure of such results using barley does not provide guidance with respect to whether or how to modify the disclosed method for use with a different graminae species such as barley in order to obtain the same results achieved when using the Glenlea wheat cultivar.

With respect to the use of various types of betaines, the scope of the rejection has been adjusted accordingly. With respect to the multiple examples of useful betaine doses and dosage regimes disclosed in the application at pages 3, 4, 8 and in Figure 1, the examples appear to be limited to betaine doses and dosage regimes useful for increasing or inducing cold or freezing tolerance using the Glenlea wheat cultivar only. Furthermore, that the specification indicates that the plant is acclimated to a temperature not lower than the coldest temperature that the plant can withstand, that information about the cold-hardiness of commercially import plants should be readily available or may be determined according to methods disclosed in the specification does not provide sufficient guidance with respect to enabling the full scope of the claimed invention

because the effect of betaine accumulation in plants is unpredictable, since different plant species may respond differently to the application and accumulation of glycine betaine.

With respect to the support disclosed for increasing or inducing salinity and water stress tolerance, Applicants' point is not germane to the pending claims, which impose no requirements with respect to salinity and water stress tolerance. With respect to the support disclosed for improving photosynthetic capacity and overall physiology at cold temperature, the disclosed results do not appear to have been achieved using the claimed method. Page 10 lines 3-6 discloses that that "During steady-state photosynthesis at the prevailing growth conditions, exposure of spring and winter wheat to 250 mM betaine resulted in small but consistently higher levels of qP and higher yields of PSII electron transport (Φe) than non-treated controls (Table 1). Thus, betaine treated spring and winter wheat seedlings appeared to exhibit a greater capacity to prevent the reduction of PSII reaction centres than non-treated controls." The specification does not disclose a method in which graminae plants are exposed to a temperature not lower than the coldest temperature the plants are capable of withstanding for a time sufficient to induce cold or freezing tolerance and administering betaine to the plants to increase betaine concentration in the plant during cold acclimation to induce cold or freezing tolerance, which further results in improving resistance to photoinhibition.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 24 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as

the invention. Claim 24 is indefinite in the recitation of "said rosacea species", as there is insufficient antecedent basis for this limitation in claim 1 from which claim 24 depends.

Claim Rejections - 35 USC § 103

Claims 10-11, 17, 21 and 39 remain rejected, and claims 1-3, 9, 12-14, 16, 18, 22, 24 and 38-41 are rejected, under 35 U.S.C. 103(a) as being unpatentable over Rajashekar et al. (Plant Physiology, 1996, Vol. 111, No. 2 SUPPL., page 70) in view of Kishitani et al. (Plant, Cell, and Environment, 1994, Vol. 17, pages 89-95), and in light of Zhao et al. (Journal of Plant Physiology, 1992, Vol. 140, pages 541-543), for the reasons of record set forth in the office action mailed September 23, 2003.

Applicant's arguments filed February 23, 2004, have been fully considered but they are not persuasive.

Applicants submit that the former wording of claim 1 did define the claimed invention by stating that the combined steps of a) and b) increased the cold or freezing tolerance of the plant over and above that induced by performing each step alone. Applicants also submit that claim 1 as amended emphasizes that there must be some concurrency between increasing betaine concentration and cold acclimation, and that dependent claim 9 further defines the invention by requiring that the steps be substantially simultaneous. Applicants further submit that the synergistic increase in freezing tolerance that results from combining betaine application and cold acclimation is surprising and unexpected, and that it would not have been obvious to one skilled in the art that combining betaine application and cold acclimation would produce such a synergistic effect. (reply pages 13-14),

Applicants' submissions are not germane to the instant rejection as the cited reference of Rajashekar et al. in fact teach a method in which the steps of betaine application and cold acclimation are combined, as Rajashekar et al. teach that "exogenous glycine betaine (2mM) was effective in inducing cold tolerance in unhardened and cold-hardening plants" (abstract lines 11-13).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Remarks

No claim is allowed.

Claims 19-20 are deemed free of the prior art due to the failure of the prior art to teach or suggest a method of increasing or inducing cold or freezing tolerance in graminae species plants

by acclimating a plant and increasing the concentration of betaine or a derivative thereof at a concentration of about 250 mM.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (571) 272-0794. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Cynthia Collins

DAVID T. FOX
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